K082793

APR - 2 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92

Sponsor:	Biomet Spine/Biomet Trauma 100 Interpace Parkway Parsippany NJ 07054
Establishment Registration Number:	2242816
Manufacturing Site	Interpore Cross International 181 Technology Dr Irvine CA 92618
Manufacturing Site Registration Number:	2029012
Contact:	Kathleen Ideo Regulatory Associate Interpore Cross International 181 Technology Dr Irvine CA 92618 (949) 453-3200
Date Prepared:	February 17, 2009
Trade/Proprietary Name:	InterGro DBM (Putty, Paste, Plus)
Common/Usual Name:	DBM Bone Graft Substitute
Classification Name:	Bone Grafting Material
Device Classification:	Class II
Regulation Number	21 CFR 888.3045
Product Codes	MQV, MBP, GXP
Predicate Device:	DynaGraft II, DBX, InterGro DBM
Device Formulation:	InterGro DBM (Putty, Paste, Plus)
Performance:	Performance standards applicable to DBM-based

products have not been published by the FDA. Interpore Cross International intends to manufacture and package this device according to the regulations and standards that are appropriate to the risk that Class II devices reasonably present. Voluntary performance standards, such as materials certifications, in-house SOP's, FDA Guidance Documents, AATB Standards and/or ASTM Standards are used as appropriate.

Device Description:

InterGro DBM is a resorbable, osteoconductive, and osteoinductive bone graft substitute that resorbs and is replaced with bone during the healing process. Its main component, demineralized cortical bone matrix (DBM), is derived from donor human tissue (allograft bone) and contains various growth factors including osteoinductive proteins. The DBM has been granulated, lyophilized and aseptically processed. In some versions of the product, calcium salt granules shall be incorporated to provide additional radiopacity, osteoconduction, and enhanced structural strength. The carrier for InterGro DBM is a resorbable, biocompatible, semi-viscous lipid. InterGro DBM is provided ready-to-use in various physical consistencies. It is packaged in various sizes by volume for single patient use.

Indications for Use:

InterGro DBM products (Putty, Paste, Plus) are to be used for filling bony voids or gaps in the extremities and pelvis that are not intrinsic to the bony stability of the structure, and as an autograft extender in the spine. InterGro Plus may also be used as a bone void filler in the spine (posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to bone. InterGro DBM may also be used for filling craniofacial defects and craniotomies that are no larger than $25cm^2$. The amount of InterGro DBM products to be used should be based on the type of procedure and size of the graft site.

Substantial Equivalence Information

Viral Inactivation Validation: The methods for processing the DBM contained in InterGro DBM were evaluated for their viral inactivation potential. A select panel of viruses representing various viral types, sizes, shapes, and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing methods for a wide range of potential human viruses.

Osteoinductive Potential: Each lot of DBM incorporated into InterGro DBM is assayed for its osteoinductive potential. The assay measures the alkaline phosphatase production of a myoblast cell line (C2C12) in the presence of human DBM compared to positive and negative controls (osteoinductive index). Results of the assay have been correlated with results from implantation of DBM into athymic rat muscle, which demonstrated a correlation coefficient of 0.88 ($p<0.0005$) and accurately predicted the *in vivo* osteoinductivity in 20 donor lots.[1]

The combination of DBM, the carrier and, in some formulations, ceramic granules has not been evaluated for osteoinductivity; therefore it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. Additionally, it is unknown how osteoinductivity of the DBM component, measured via the *in-vitro* "C2C12" bioassay will correlate with human clinical performance of InterGro DBM products.

[1]Han B, Tang B, and Nimni M. Quantitative and Sensitive in vitro Assay for Osteoinductive Activity of Demineralized Bone Matrix. J Ortho Res, 2003, 21:648-54.

Product Performance Testing: Performance of InterGro DBM was evaluated in an animal model by radiographic and histological methods.

Conclusion:

The safety and effectiveness of InterGro DBM is adequately supported by the substantial equivalence information, materials data, and testing results provided within this premarket notification.

InterGro DBM was found to be substantially equivalent to the predicate devices based on the intended use, base materials, select performance properties, and use of a handling material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Spine/Biomet Trauma
% Ms. Kathleen Ideo
100 Interpace Parkway
Parsippany, New Jersey 07054

APR - 2 2009

Re: K082793
Trade/Device Name: InterGro® DBM (Putty, Paste, Plus)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV, MBP, GXP
Product March 25, 2009
Received: March 26, 2009

Dear Ms. Ideo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson for

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082793

Device Name: InterGro® DBM (Putty, Paste, Plus)

Indications for Use:
InterGro DBM products (Putty, Paste, Plus) are to be used for filling bony voids or gaps in the extremities and pelvis that are not intrinsic to the bony stability of the structure, and as an autograft extender in the spine. InterGro Plus may also be used as a bone void filler in the spine (posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to bone. InterGro DBM may also be used for filling craniofacial defects and craniotomies that are no larger than $25cm^2$. The amount of InterGro DBM products to be used should be based on the type of procedure and size of the graft site.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MVH

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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